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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------|-------------|----------------------|---------------------|------------------|
| 10/019,164        | 12/20/2001  | Benjamin J. Metcalf  | 33,484-00           | 3977             |
| 25291             | 7590        | 01/25/2008           | EXAMINER            |                  |
| WYETH             |             |                      | DUFFY, PATRICIA ANN |                  |
| PATENT LAW GROUP  |             |                      | ART UNIT            | PAPER NUMBER     |
| 5 GIRALDA FARMS   |             |                      | 1645                |                  |
| MADISON, NJ 07940 |             |                      |                     |                  |
|                   |             |                      | MAIL DATE           | DELIVERY MODE    |
|                   |             |                      | 01/25/2008          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |                   |                      |
|------------------------------|-------------------|----------------------|
| <b>Office Action Summary</b> | Application No.   | Applicant(s)         |
|                              | 10/019,164        | METCALF, BENJAMIN J. |
|                              | Examiner          | Art Unit             |
|                              | Patricia A. Duffy | 1645                 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

1) Responsive to communication(s) filed on 11-2-07.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

4) Claim(s) 1,2,5,8,18,20 and 21 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1,2,5,8,18,20 and 21 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

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### RESPONSE TO AMENDMENT

The amendment filed 11-2-07 has been entered into the record. Claims 3, 4, 6, 7, 9-17, 19, and 22 have been cancelled. Claims 1, 2, 5, 8, 18, 20 and 21 are pending and are under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

#### *Rejections Withdrawn*

The rejection of claims 1-8 and 18-22 under 35 USC 112, second paragraph as being indefinite for failing to particular point out and distinctly claim the subject matter which applicant regards as the invention for reasons made of record is withdrawn in view of Applicants amendments to the claims.

The rejection of claims 1-8 and 18-22 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendment to the claims.

Any art rejection not explicitly maintained herein is withdrawn based on Applicants amendment to the claims.

#### *Rejections Maintained*

Claims 1, 2 5, 8, 18 and 21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Anilionis et al (WO 90/02557, published 22 March 1990) in view of Nelson et al (Infection and Immunity, 56(1):128-134, 1988) and Guzman et al (Journal of Bacteriology, 177(14):4121-4130, 1995) and Makrides et al (Microbiological Reveiws, 60(3):512-538, Sept 1996) for reasons made of record in the Office Action mailed 7-2-07.

Applicant's arguments have been carefully considered but are not persuasive.

Applicants argue that rejection is improper because Anilionis does use strong promoters and obtains high levels of transcription (albeit with reduced lipidation) for the purposes of vaccine or medicament production whereas Guzman et al and Makrides et al are directed to research study/experimentation and not medicament production. This is not persuasive, all of the references address optimization of heterologous protein expression in *E. coli* and Anilionis et al teach that Anilionis et al specifically teach that bacterial host cell strains and expression vectors may be chosen which inhibit action of the promoter unless specifically induced (page 29, lines 27-30). Guzman et al (Journal of Bacteriology, 177(14):4121-4130, 1995) teach vectors for use in *E. coli* that are both positively and negatively modulated, have a high level of expression and comprise the arabinose PBAD promoter and are not expressed in the absence of the inducer arabinose. Guzman et al teach the vector pBAD18-cm (see Figure 1A, page 4122). pBAD18-cm is the same vector utilized in the instant application to express the P6 protein (page 16, line 17-24) from claimed plasmid pPX4020. Applicants argue that one skilled in the art would reach to Anilines et al promoters and not that of Guzman et al. This is not persuasive, Anilines et al teach the functionalities of other promoters can be chosen as is relied upon and specifically pointed out. Anilionis et al does not teach that only their promoters would work.. it directs the skilled artisan to others that would work and specifically direct to those that are inhibited unless specifically induced. The pBAD promoter of Guzman et al and in particular the vector pBAD18-cm (see Figure 1A, page 4122) meets the criteria of Anilines et al. pBAD18-cm is the same vector utilized in the instant application to express the P6 protein (page 16, line 17-24) from claimed plasmid pPX4020. Applicant's arguments indicate that the analysis must be explicit. The analysis is explicit and each of the structural requirements of the plasmid requirement are met by the art as combined. Anilionis et al direct one to the specific functionalities of the optional promoters. The secondary art provides those functionalities and one of skill in the art would recognize

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such. Applicants ignore Anilionis et al teaching which directs one to the use of additional promoters for expression to provide a specific functionality and specifically teaches any number of suitable promoters can be used. Guzman et al teach a promoter system with the functionality suggested by Anilionis et al. The promoter system of Guzman et al would necessarily be recognized by the art as a tightly regulated arabinose inducible promoter. Makrides et al teach at Table 1 page 514, that araBAD and T7 are promoters used for the high-level expression of genes in *E. coli*. As such, the combination factually meets and suggests the claimed invention. Finally, Applicants argue hindsight reconstruction. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Claims 18 and 21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Anilionis et al (WO 90/02557, published 22 March 1990) in view of Nelson et al (Infection and Immunity, 56(1):128-134, 1988), Mertens et al (Gene, 164:9-15, 1995) and Makrides et al (Microbiological Reviews, 60(3):512-538, Sept 1996) for reasons made of record in the Office Action mailed 7-2-07.

Applicants argue that the amendment to the claims to recite directed to a promoter "consisting of a T7 promoter" and that the art teaches away from the use of the T7 promoter alone. This is not persuasive. The claims are directed to "A plasmid containing a tightly regulated promoter consisting of a T 7 promoter...". The claim term "containing" is construed as open language and does not exclude the presence of other promoters in the plasmid. The transitional term "comprising", which is synonymous with

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"including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., > Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term comprising,' the terms containing' and mixture' are open-ended.").< Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003). As such, the rejection is maintained in that the plasmid is not seen as limited to having only the T7 promoter.

Claim 20 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Anilionis et al (WO 90/02557, published 22 March 1990), Nelson et al (Infection and Immunity, 56(1):128-134, 1988), Mertens et al (Gene, 164:9-15, 1995) and Makrides et al (Microbiological Reveiws, 60(3):512-538, Sept 1996) as combined *supra* for claims 1-3, 6, 8, 18 and 21 and further in view of Novagen Inc., admittedly commercially available in specification page 15, line 34) for reasons made of record in the Office Action mailed 7-2-07.

Applicant's arguments have been carefully considered but are not persuasive. Applicants argue that the combination describes a different promoter system than that as claimed. This is not persuasive, the pPX4019 is the same promoter system as present in the plasmid designated pPX4019. Applicants should point to the structural difference between the claimed plasmid and that of Novagen et al as used in the art as combined.

#### *Status of Claims*

Claims 1, 2, 5, 8, 18, 20 and 21 stand rejected.

#### *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 7:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Shanon Foley can be reached on 571-272-0898.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

*Patricia A. Duffy*  
Patricia A. Duffy

Primary Examiner  
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